

Stark Law Update: Irrational Laws Rigidly Applied

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Agenda

- Introduction: Why are we in this mess?
- Stark Law basics
- The Stark 'Exceptions'
- Pitfalls and challenges
- Closing remarks



Why are in this mess?

- Money corrupts clinical decision-making
- “Gatekeeper” -- government (and private payers) do not pay for services unless they are ordered by a physician
- Age-old temptation to reward the Gatekeeper
- Promote healthcare as a social good, not just a business for physicians and others



Why are we in this mess?

- Stark law – any financial relationship with a referring physician is prohibited unless it fits into an exception
- Anti-kickback law – it’s a crime to financially induce referrals
- False Claims Act – if billing for services resulting from the Stark violation, return triple the money plus penalties
- Tax exempt laws – hospitals exist to serve the public, not individuals (e.g., physicians); FMV is the cap



Stark Basics: Fundamental Prohibition

- Start with presumption that entity (hospital, lab, etc) CANNOT bill Medicare for any Designated Health Service ordered by a physician with whom entity has a financial relationship.
- Billing prohibition waived only if elements of an applicable exception are fully met.
- Physician in relationship may not refer to entity unless the relationship meets Stark exception.
- There is NO guarantee an exception is available.
- Lack of bad intent or presence of good intent is IRRELEVANT.



Stark Basics: Definition of Financial Relationship

- *Financial Relationship* • employee
- Ownership and • employer
- compensation • partner
- relationship broadly • investor
- defined • contractor
- • lessor/lessee
- • medical director
- • Gifts, honoraria, discounts



Stark Basics: Definition of Physician

- husband or wife
- birth or adoptive parent
- birth or adoptive child
- birth or adoptive sibling
- stepparent
- stepchild
- stepbrother / stepsister
- father/mother-in-law
- son/daughter-in-law
- brother/sister-in-law
- grandparent
- grandchild
- spouse of a grandparent
- spouse of a grandchild



Stark Basics: Definition of Designated Health Service

Generally:

1. Clinical lab services
2. Therapies (PT, OT, ST)
3. Imaging services
4. Radiation therapy
5. DME and supplies
6. Parental/Internal nutrition & supplies
7. Prosthetics/orthotics
8. Home health services (but not Hospices)
9. Outpatient prescription drugs
10. IP & OP Hospital



Stark Basics: Traps For the Unwary

- Underlying requirement that all agreements be ‘commercially reasonable’
- Requires “perfect” compliance or penalties imposed
- Rules constantly changing and frequently don’t take into account the way business is done
- Consequences disproportionate to harm
- The more important the physician/group, the bigger the risk
- Watch out for physician-owned entities (equipment leases, device companies)



Stark Exceptions: Ownership

- Publicly traded companies
- Mutual funds
- Certain rural providers



Stark Exceptions: Ownership & Compensation

- Physician Services within a ‘group’
- In-office ancillary services
- Services provided by an organization to its enrollees
- Academic medical center services
- Implants furnished by ASC
- EPO/dialysis related drugs
- Proactive screening/immunizations



Stark Exceptions: Compensation

- Personal services
- Fair Market Value
- Isolated Transactions (careful!)
- Unrelated to DHS (careful!)
- Office space/equipment rental
- Physician recruitment agreements
- Employment (limited in CA/NV)
- Medical Staff Incidental Benefits
- Indirect Compensation
- Non-monetary Compensation
- Others



Stark Basics: You Need Competent Counsel

No Contract/No Service, Use or Occupancy (note: there is no emergency exception)

Contract: Written Agreement is one that is:

1. Commercially reasonable
2. Prepared by **competent** legal counsel or uses template approved by **competent** legal counsel
3. FMV documented
4. Signed and dated by both parties before services, payment, occupancy begins



Stark Basics: What this means for you

No exception/Lapsed exception = can't do it!

- Expired contract = no billing past expiration
- Services performed before signed contract = either no billing Medicare or no payment to physician for her services before signing
- Refund program money for all services ordered by physician during 'period of disallowance' (can be very expensive)
- Disclose to government; ask forgiveness, but no assurances government will be reasonable



Stark Basics: Record Keeping Requirements

- Obligation to retain agreements for 4 years beyond expiration
- Must produce **agreement** and **evidence of fair market value** within 30 days of HHS Secretary request. Failure will result in penalty of \$10,000 per day.
- Government may ask for all agreements at once



Summary

- **Laws complex**
- **Government means business**
 - “business” means penalties, fines and/or jail for non-compliance
- **Robust internal controls are essential**
- **Legal and Compliance should serve as a resource**
- **Prevention easier than cure**

